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(57) Abstract

The invention relates to denture cleansing compositions, in tablet form, comprising a film–forming oil, an effervescence generator, from about 0.1 to about 3 % of a foam–forming surfactant, and a water–insoluble, wettable, particulate foam stabiliser having a weight average particle size of from about 20 to about 400 μm, the foam stabiliser having a Foam Stabilising Index of greater than 120. The compositions of the invention have high, prolonged foaming activity and help prevent plaque build–up on dentures or teeth. The tablets resist breakage and dissolve rapidly.

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DENTURE CLEANSING TABLETS

Technical Field

The present invention relates to denture cleansing compositions in tablet form. In particular, the invention relates to denture cleansing tablets which effervesce when added to water, producing a copious foam which helps suspend particulate matter. The compositions deliver enhanced plaque prevention benefits together with excellent cleansing performance and in-use performance characteristics.

Background

Tablets and powders for cleansing dentures and the like are well known in the art. The aim of a denture cleanser product is to clean the denture as fully and as quickly as possible and especially to remove the accumulation of plaque, mucilaginous and bacterial deposits which collect while the denture is being worn. To wear a denture which has not been completely cleaned of plaque and bacterial deposits is not only unhygienic but can also within a short space of time result in a detrimental effect on the mucous membrane. Moreover bacterial deposits can lead to so-called bacterial corrosion of the plastics material used to produce the denture with consequent colour change and malodour formation.

Denture cleansers are usually used by being dissolved in a glass of warm water. To be effective, it is first necessary for the tablet or powder to dissolve rapidly. This is particularly true of the compressed tablet form. Effervescence, which can be generated as the tablet dissolves, assists in tablet break-up and the foam generated also helps signal efficacy to the consumer. Surfactants in the formulation enhance foam generation and cleaning. It is further desirable to deposit an agent on the teeth or dentures which prevents further plaque build-up. Many silicones are suitable for this purpose as described, for example, in WO 96/19563 and WO 96/19191. However the silicones can also act as foam suppressors. Whilst a surfactant is desirable for foam building, high levels can also inhibit the silicone deposition and make compressed tablets slow to dissolve. In this context it is useful to employ a foam stabiliser which inhibits foam collapse, thereby maintaining foam levels without employing undesirably high surfactant levels. It has now been found that certain particulate materials can act as effective foam stabilisers but that their physical properties must be carefully selected to avoid adversely affecting tablet strength and disintegration.

Accordingly, it is an object of this invention to provide a denture cleansing tablet which can prevent plaque build-up, yet have a good foaming action and high tablet strength.

It is a further object of this invention to provide a denture cleansing tablet which is produces a long-lasting foam.

It is yet a further object of this invention to provide a denture cleansing tablet which is resistant to breakage and dissolve rapidly in solution.

Summary Of The Invention

The invention provides a denture cleansing composition, in tablet form, comprising a film-forming oil, an effervescence generator, from about 0.1 to about 3% of a foam-forming surfactant, and a water-insoluble, wettable, particulate foam stabiliser having a weight average particle size of from about 20 to about 400 μm, the foam stabiliser having a Foam Stabilising Index of greater than 120.

The compositions of the invention have high foaming activity and help prevent plaque build-up on dentures or teeth. The tablets resist breakage and dissolve rapidly.

All percentages and ratios herein are by weight of the composition, unless otherwise indicated.

Detailed Description of the Invention

The compositions of the invention are in tablet form, the tablets can be single or multi-layered. The tablets can be made from a granular or powdered composition using any of the methods known in the art, direct compression is preferred.

The compositions comprise, as essential components, a film-forming oil, an effervescence generator, from about 0.1 to about 3% of a foam-forming surfactant, and a water-insoluble, wettable, particulate foam stabiliser having a weight average particle size of from about 20 to about 400 μm and which has a Foam Stabilising Index (as defined herein) of greater than 120. The composition can additionally comprise several optional components. The essential and optional components will now be described in turn.

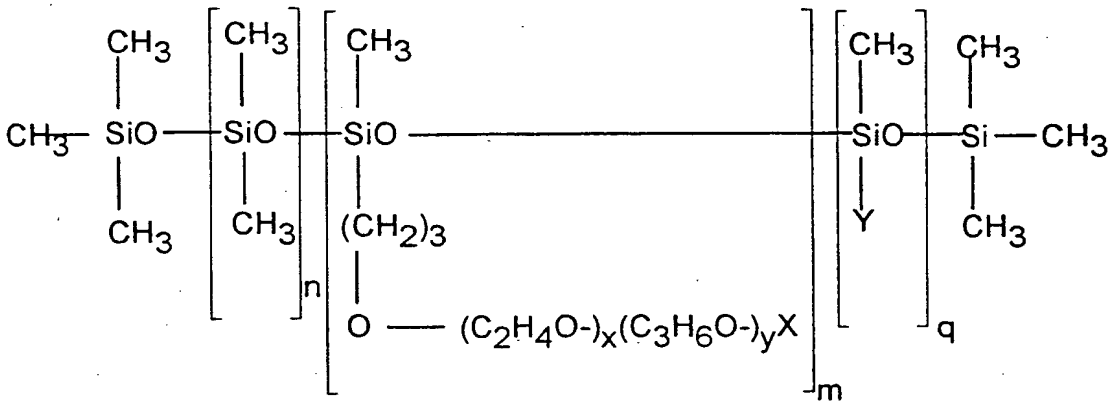
Film-forming oil

A first essential ingredient of the powder is a film-forming oil. By "film-forming oil" herein is meant a material, or mixture of materials, that is insoluble in or immiscible with water at 40°C and is liquid at 40°C and that will spread on an acrylic plate at that temperature. More particularly the oil preferably has a contact angle with acrylic of less than 90°, more preferably less than 70°, and especially less than 50° at 40°C. Suitable film-forming oils include hydrocarbons, fluorocarbons, mineral oils and silicone oils. Highly preferred herein are silicone oils. By "silicone oil" is meant a polymer with a

silicon or siloxane backbone. Suitable classes of silicone oils include, but are not limited to, dimethicones, dimethiconols, dimethicone copolyols and aminoalkylsilicones.

A highly preferred silicone oil is a dimethicone copolyol or aminoalkylsilicone antiplaque agent such as those described in WO 96/19563 and WO 96/19554.

Preferred for use herein are alkyl or alkoxy dimethicone copolyols having the formula (I):

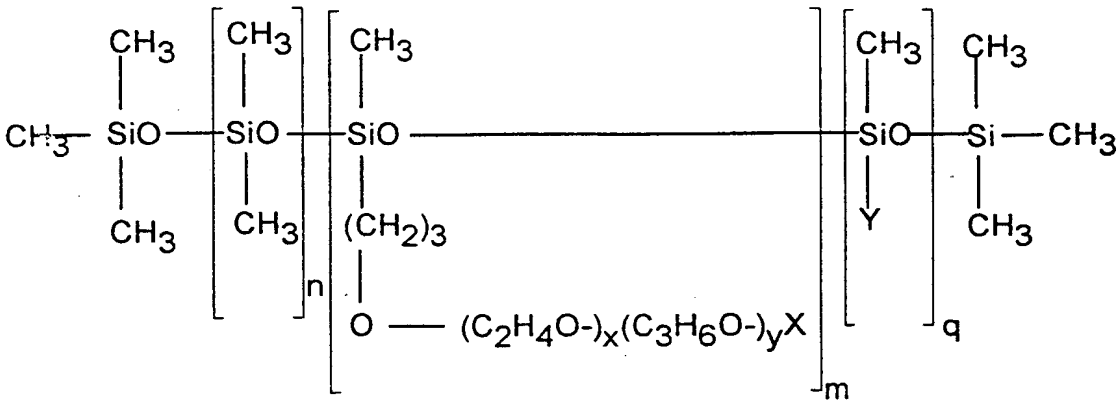


wherein X is selected from hydrogen, alkyl, alkoxy and acyl groups having from about 1 to about 16 carbon atoms, Y is selected from alkyl and alkoxy groups having from about 8 to about 22 carbon atoms, n is from 0 to about 200, m is from about 1 to about 40, q is from about 1 to about 100, the molecular weight of the residue $(C_2H_4O\text{-})_x(C_3H_6O\text{-})_yX$ is from about 50 to about 2000, preferably from about 250 to about 1000 and x and y are such that the weight ratio of oxyethylene:oxypropylene is from 100:0 to 0:100, preferably from 100:0 to about 20:80.

In preferred embodiments, the dimethicone copolyol is selected from C_{12} to C_{20} alkyl dimethicone copolyols and mixtures thereof. Highly preferred is cetyl dimethicone copolyol marketed under the Trade Name Abil EM90.

The silicone antiplaque agent is generally present in a level of from about 0.05% to about 5%, preferably from about 0.1% to about 3%, more preferably from about 0.2% to about 1.5% by weight.

A desirable additional ingredient of the denture cleansing compositions of the invention is a silicone surfactant having the general formula (I)



wherein X is selected from hydrogen, alkyl, alkoxy and acyl groups having from about 1 to about 16 carbon atoms, Y is CH_3, q is 0, n is from about 1 to about 100, m is from about 1 to about 40, the molecular weight of the residue $(C_2H_4O\text{-})_x(C_3H_6O\text{-})_yX$ is from about 50 to about 2000, and x and y are such that the weight ratio of oxyethylene:oxypropylene is from about 100:0 to about 0:100.

The silicone surfactant, itself a dimethicone copolyol, assists in subsequent re-dispersion of the silicone antiplaque agent in aqueous media whilst still allowing the antiplaque agent to deposit onto surfaces such as teeth, gums or artificial dentures. In preferred embodiments, the silicone surfactant is selected from dimethicone copolyols having a HLB value in the range from about 8 to about 14, more preferably from about 9 to about 12, and mixtures thereof. A suitable example of such a material is that marketed under the Trade Name Silwet L7230. The silicone surfactant is generally present in a level of from about 0.1% to about 5%, preferably from about 0.2% to about 3%, more preferably from about 0.3% to about 1.5% by weight of the composition. In general, the level of the silicone surfactant should be chosen such that the ratio of silicone surfactant to the silicone antiplaque agent is from about 0.5:1 to about 5:1, more preferably from about 0.8:1 to about 3:1, most preferably from about 0.9:1 to about 2:1 by weight.

A preferred method of incorporating the silicone antiplaque agent and/or the silicone surfactant is via a spray-dried powder as will be described further below.

The spray-dried powder includes a water-soluble carrier. By "water-soluble carrier" herein is meant any material which is has a solid at 25°C, is capable of being processed into granular form, is capable of being made into a clear or translucent aqueous solution at 25°C at a level of about 1% by weight of the solution, and is safe for use on human skin or mucosa. Suitable carriers include, but are not limited to, polyethylene glycols, starches, gum arabic, gum tragacanth, gum acacia, carrageenans, cellulose derivatives and

mixtures thereof. Preferably, the carrier is capable of being spray-dried into a free-flowing powder. In especially preferred embodiments the water-soluble carrier is a food-grade carrier selected from starches, gum arabic, gum tragacanth, gum acacia and mixtures thereof. A particularly preferred carrier is a modified starch available under the tradename Capsul E from National Starch & Chemical of Manchester, UK. Optionally, the carrier can comprise a sugar alcohol or saccharide, such as sorbitol, mannitol or maltodextrin. Without being limited by theory, it is believed that the sugar alcohol or saccharide helps to form a film on the surface of the particle which improves the encapsulation of the oil by the powder particle. A preferred carrier consists of a mixture of starch and sorbitol, preferably from about 2.5:1 to about 4:1, more especially about 3:1 by weight of the carrier. A mixture of gum acacia and maltodextrin in the ratio of from about 1:2 to about 2:1 can also suitably be used.

The water-soluble carrier is generally present in a level of from about 50% to about 99%, preferably from about 60% to about 90%, more preferably from about 65% to about 90% by weight of the spray-dried powder.

The powders are generally in granular form, wherein the powder has a volume average particle size in the range from about 20 μm to about 500 μm, preferably from about 50 μm to about 250 μm, more preferably from about 80 μm to about 150 μm. The average particle size can be measured using standard sieve techniques well known in the art. Alternatively, the average particle size can be measured using a commercial instrument such as the Malvern Mastersizer X available from Malvern Instruments Ltd. of Malvern, Worcs., UK,. The Mastersizer is preferably fitted with a MSX64 Dry Powder Feeder and a a 300 mm lens for measuring particles in the range 1.2 to 600 microns.

The powders can be prepared by dispersing the silicone antiplaque agent and/or the silicone surfactant in a aqueous solution of the water-soluble carrier and spray-drying the resultant dispersion. Whilst, the strength of the carrier solution is not critical, it will be understood that very dilute solutions will require considerable input of energy to dry. Suitably the aqueous solution of the carrier will comprise from about 25% to about 50%, more preferably from about 30% to about 45%, more especially from about 35% to about 40% of the carrier by weight of the solution.

In order that the powder hereof has the desired properties, it is important to control the silicone droplet size within the dispersion. In general, the silicone should be present in the dispersion in the form of discrete droplets having a volume average droplet size in the range from about 0.5 μm to about 20 μm. Further, the ratio of the average spray-dried particle size to the average droplet size should be at least about 2.5:1. In preferred

embodiments the ratio of the average spray-dried particle size to the average droplet size is at least about 4:1, preferably at least about 6:1, more preferably at least about 10:1. Smaller droplets, in relation to the final spray-dried powder particle size, serve to improve the flow characteristics and further processability of the powder. The desired droplet size can be achieved by using shear mixing to form the dispersion and measured by using phase contrast photomicroscopy. A suitable procedure is to use, for example, a Nikon Labophot 2 at 400x magnification with fixed focal length and fitted with a graticule. It will be appreciated that a suitable number of observations need to be made to reduce the sampling error. The precise number to be made will depend, for example, upon the droplet size distribution achieved. The dispersion is mixed, with adjustment of the shear rate if necessary, until the desired droplet size is attained.

The spray-dried silicone powders preferably also include a flavour or perfume oil. As used herein, the term 'flavour or perfume oil' means those flavour or perfume essences and equivalent synthetic ingredients which are added to the powder for the principal purpose of modifying the taste and / or odour or other organoleptic sensations of the powder or the final product into which the powder is incorporated. It excludes silicone antiplaque agents and silicone surfactants as described above but includes lipophilic physiological cooling agents.

Lipophilic flavorants suitable for use herein comprise one or more flavor components selected from wintergreen oil, oregano oil, bay leaf oil, peppermint oil, spearmint oil, clove oil, sage oil, sassafras oil, lemon oil, orange oil, anise oil, benzaldehyde, bitter almond oil, camphor, cedar leaf oil, marjoram oil, citronella oil, lavendar oil, mustard oil, pine oil, pine needle oil, rosemary oil, thyme oil, cinnamon leaf oil, and mixtures thereof.

Physiological cooling agents suitable for use herein include carboxamides, menthane esters and menthane ethers, and mixtures thereof. Examples of preferred cooling agents suitable for use herein include Takasago 10 [3-l-menthoxy propan-1,2-diol (MPD)], from Takasago International Corporation, and carboxamides such as those described in US-A-4,136,163, January 23, 1979 to Watson et al., and US-A-4,230, 688, October 28, 1980 to Rawsell et al.

The amount of flavour or perfume oil employed is normally a matter of preference subject to such factors as flavour type, base type and strength desired. The level of flavour or perfume oil in the compositions of the invention is generally in the range from about 1% to about 15% by weight of the spray-dried powder. Preferably the flavour or perfume oil is incorporated by making an intimate premix of the silicone antiplaque agent and the

flavour or perfume oil, along with the silicone surfactant, where used, and then forming a dispersion of the premix in the carrier solution as described above.

It has been found that forming an intimate admixture of the flavour or perfume oil with the silicone antiplaque agent prior to dispersing the mixture in the aqueous carrier solution acts to reduce the droplet size of the dispersed oil and improve the flow characteristics and further processability of the powder.

It has further been found that the flavour or perfume oil being in intimate admixture with the silicone antiplaque agent acts to enhance the substantivity of the flavour or perfume oil to teeth and/or dentures, thereby providing enhanced and/or sustained organoleptic impact. In the same way, lipophilic antimicrobial compounds can advantageously be included along in the same manner as the flavour or perfume oil, to provide enhanced and/or sustained antimicrobial efficacy. Suitable lipophilic antimicrobial compounds for use herein include thymol, menthol, triclosan, 4-hexylresorcinol, phenol, eucalyptol, benzoic acid, benzoyl peroxide, butyl paraben, methyl paraben, propyl paraben, salicylamides, and mixtures thereof.

Effervescence Generator

A second essential feature of the present invention is an effervescence generator which helps to disintegrate the tablet and to create the initial foam. Generally, the effervescence generator is an oxygen effervescence generator or a carbon dioxide effervescence generator or a mixture of the two. Suitable oxygen effervescence generators include persalt bleaching agents. The bleaching agent can be selected from any of the well-known bleaching agents known for use in denture cleansers such as the alkali metal and ammonium persulfates, perborates, percarbonates and perphosphates and the alkali metal and alkaline earth metal peroxides. Examples of suitable bleaching agents include potassium, ammonium, sodium and lithium persulfates and perborate mono- and tetrahydrates, sodium pyrophosphate peroxyhydrate and magnesium, calcium, strontium and zinc peroxides. Of these, however, the alkali metal persulfates, perborates and mixtures thereof are preferred for use herein, highly preferred being the alkali metal perborates.

The amount of bleaching agent in the total composition is generally from about 5% to about 70%, preferably from about 20% to about 60%. Preferred compositions comprise both a persulphate salt and a perborate salt. The persulphate salt and perborate salt can be in any ratio but it has been found that better foaming is achieved with a weight ratio of from about 0.8:1 to about 5:1, preferably from about 1.5:1 to about 4:1, more preferably

from about 2:1 to about 3.5:1. Both of these ingredients are effective bleaches which contribute to the stain removal activity of the cleansing compositions.

Suitable sources of the persulphate salt are the alkali metal and ammonium persulphates. Preferred is potassium monopersulphate or a mixed salt thereof. Particularly preferred are the commercially available mixed salts such as Caroat®, marketed by Degussa, and Oxone®, marketed by E I du Pont de Nemours Co. and which are a 2:1:1 mixture of potassium monopersulphate, potassium sulphate and potassium bisulphate and which have an active oxygen content of about 4.5%. The level of persulphate salt is suitably from about 5% to about 70%, preferably from about 20% to about 60%, more preferably from about 35% to about 55% by weight of the composition.

Suitable perborate salts are the alkali metal perborates, particularly sodium perborate. Sodium perborate is preferably used as the monohydrate or anhydrous form, although the tetrahydrate can also be used. Especially preferred is the monohydrate or mixtures of the monohydrate and anhydrous forms of sodium perborate. Suitably the ratio of anhydrous to monohydrate is from 0:100 to about 30:70. The total level of perborate salt is generally from about 6% to about 30%, preferably from about 10% to about 25%, more preferably from about 15% to about 20% by weight of the composition.

The perborate salt / persulphate salt combinations described above give rise to oxygen effervescence. In preferred embodiments an additional, carbon dioxide effervescence generator comprising a carbonate salt and an acid is included. The carbon dioxide effervescence generator is useful for providing rapid, initial effervescence when the composition is first added to water which will usually be about neutral pH but may be slightly acidic. The initial effervescence is valuable for dispersing the solid composition in water and assisting its dissolution by providing turbulence. Preferred carbonate salts are the rapidly soluble alkali metal carbonates, such as sodium carbonate, potassium carbonate and mixtures thereof, especially sodium carbonate. The carbonate salt is provided in admixture with at least one non-toxic, physiologically-acceptable organic or inorganic acid, such as tartaric, fumaric, citric, malic, maleic, gluconic, succinic, salicylic, adipic or sulphamic acid, sodium fumarate, sodium or potassium acid phosphates, betaine hydrochloride or mixtures thereof. Of these, citric acid is preferred.

In preferred denture cleansing compositions in tablet form, the carbon dioxide effervescence generator takes the form of a solid premix comprising sodium carbonate and citric acid, which in the presence of water releases carbon dioxide with effervescence. The premix can comprise further additives and excipients such as sodium bicarbonate and dye.

It has further been found that whilst it is valuable to have the carbonate salt present, too much carbon dioxide can lead to early foam collapse. For this reason the proportion of carbonate is preferably similar to or below that of the perborate salt so that oxygen effervescence predominates once the composition has started to fully dissolve. The weight ratio of the perborate salt to the carbonate salt, where both are used, is suitably in the range of from about 5:1 to about 0.8:1, preferably from about 1.5:1 to about 0.9:1, more preferably about 1:1.

Where used, the carbonate salt generally comprises from about 1% to about 30%, preferably from about 5% to about 25%, more preferably from about 10% to about 20% of the total composition. The acid component generally comprises from about 2% to about 15%, preferably from about 3% to about 10% of the total composition.

Foam-forming surfactant

A third essential feature of the present invention is a foam-forming surfactant, which can be selected from anionic surfactants, nonionic surfactants, amphoteric surfactants and mixtures thereof. The phrase 'foam-forming surfactant' as used herein excludes silicone surfactants as described hereinbefore. The foam-forming surfactant used in the denture cleansing compositions of the invention can be selected from the many available that are compatible with the other ingredients of the composition, both in the dry state and in solution. Preferably the surfactant includes a C10 - C22 branched or linear alkyl chain, more preferably a C12 - C18 branched or linear alkyl chain.

Suitable anionic surfactants include alkyl sulphates, such as sodium lauryl sulphate, alkyl ether sulphates, alkyl aryl sulphonates such as sodium dodecyl benzene sulphonate (SDBS), alkyl sarcosinates, alkyl sulphoacetates and alkyl sulphosuccinates. A highly preferred anionic surface active agent is sodium lauryl sulphoacetate, commercially available as Lathanol® powder. It has also been found that the use of a surfactant mixture, comprising a primary surfactant and an additional co-surfactant, can boost foaming and reduce the total surfactant level. The total amount of foam-forming surfactant comprises from about 0.1 to about 3%, preferably from about 0.2% to about 2%, more preferably from about 0.3% to about 1.5% by weight of the composition; suitable levels of co-surfactant are from about 0.05% to about 1%, preferably from about 0.1% to about 0.5% by weight of the composition. If the total level of foam-forming surfactant is too high then the compositions, especially tabletted compositions, can become slow to dissolve. If the level is too low then foaming is impaired.

Suitable non-ionic and ampholytic surface active agents include, for example, condensation products of alkylene oxides such as ethylene or propylene oxide with fatty

alcohols, phenols, fatty amines or fatty acid alkanolamides, the fatty acid alkanolamides themselves, esters of long-chained (C_8-C_{22}) fatty acids with polyalcohols or sugars, for example glycerylmonostearate or saccharose monolaurate or sorbitolpolyoxyethylene-mono-or di-stearate, betaines, sulphobetaines or long-chain alkylaminocarboxylic acids.

A preferred feature of the compositions of the present invention is that the silicone oil and the foam-forming surfactant are in discrete, separate granules. By 'discrete, separate granules' is meant that the foam-forming surfactant is incorporated into a distinctly separate granule from the silicone oil. It has been found that keeping the foam-forming surfactant physically separate from the silicone oil helps prevent the surfactant interfering with the silicone deposition process. One method of achieving this is to form a spray-dried powder comprising the silicone oil, as described above and to either prepare a separate granular premix comprising the foam-forming surfactant, or to include the foam-forming surfactant with the excipients in the final mixing process prior to tabletting. It has been found that when the foam-forming surfactant is included with the excipients it can have a binding effect and eliminate or substantially reduce the need for additional binders such as polyethylene glycols which can have the effect of slowing down tablet disintegration.

Foam stabiliser

A further essential feature of the present invention is a water-insoluble, wettable, particulate foam stabiliser having a weight average particle size of from about 1 to about 400 μm and which has a Foam Stabilising Index of greater than 120. Without wishing to be bound by theory, it is believed that the foam stabiliser acts to physically prevent water draining out of the foam bubbles. In order to perform this function it preferably remains as a discrete particle after the tablet is dissolved. The foam stabiliser is a water-insoluble material. By "water-insoluble" is meant that the material will not form a 1% w/w clear or translucent solution in distilled water at 25°C. The foam stabiliser is preferably water-insoluble in distilled water at 40°C. The foam stabiliser is nevertheless wettable. By "wettable" is meant that the material will absorb water and is preferably dispersible in water. Preferably the foam stabiliser has a contact angle with distilled water of less than 90°, more preferably less than 70°, and especially less than 50° at 25°C.

The weight average particle size can conveniently be determined by a gravimetric analysis using a standard series of mesh sieves. Particles remaining on one mesh size but passing through the next larger mesh in the series are assumed to have an average particle size which is the average of the two mesh measurements. Preferably, the particulate foam stabiliser has a weight average particle size of from about 50 to about 400 μm, more

preferably from about 100 to about 300 μm and especially from about 150 to about 250 μm. It is further preferred to have less than 2% by weight of the particles passing through a 20 μm mesh, more preferably less than 2% by weight of the particles passing through a 100 μm mesh, and less than 2% greater than 400 μm. By controlling the particle size it has been found possible to achieve both good foam stabilisation and good tabletting properties. In particular, tablet strength is improved by not using too fine a particle size.

The foam stabiliser has a Foam Stabilising Index of greater than 120, preferably greater than 140 and more preferably greater than 150. As used herein the term "Foam Stabilising Index" is 100 times the ratio of the Foam Height of the composition including 1% by weight of the foam stabiliser to the Foam Height of the composition excluding the foam stabiliser. Foam Height is measured as follows.

150 ml of distilled water at 40°C is measured into a 250 ml pyrex beaker with an internal diameter of 67mm. One 2.5g tablet of the composition is placed into the beaker and a stop watch is started. The maximum height of the foam produced is measured every minute through the side of the beaker using a caliper. Normally the tablet will be dissolved fully within five minutes. If the tablet is not dissolved fully within ten minutes the test samples should be ground and the test repeated. The maximum foam height after fifteen minutes, averaged across five different samples is the Foam Height as used herein.

Suitable foam stabilisers for use herein include powdered and microcrystalline cellulose, cellulose esters such as cellulose acetate phthalate and cellulose ethers. Highly preferred for use herein is microcrystalline cellulose. Non-hydrated silicas can also be used provided the particle size is large enough. Hydrated silicas are generally not useful as foam stabilisers. The foam stabiliser can comprise both cellulose materials and non-hydrated silicas.

The foam stabiliser generally comprises from about 0.1 to about 3%, preferably from about 0.5% to about 2%, more preferably from about 0.7% to about 1.3% by weight of the composition.

Optional components

Denture cleansing compositions of the invention can be supplemented by other usual components of such formulations, especially bleach activators, desiccants, chelating agents, enzymes, flavours, physiological cooling agents, antimicrobial compounds, dyestuffs, sweeteners, tablet binders and fillers, additional water-soluble foam stabilisers such as the fatty acid sugar esters, preservatives, lubricants such as talc, magnesium

stearate, etc. The free moisture content of the final composition is desirably less than about 1% and especially less than about 0.5%.

An especially preferred additional component of the present invention is a bleach activator. Preferred bleach activators are described in detail in WO 96/19563. Especially preferred as a bleach activator is tetraacetyl ethylene diamine (TAED).

The level of bleach activator by weight of the total composition is preferably from about 0.1% to about 10%, more preferably from about 0.5% to about 5%.

Tablet binders and fillers suitable for use herein include polyvinyl-pyrrolidone, poly (oxyethylene) of molecular weight 20,000 to 500,000, polyethyleneglycols of molecular weight of from about 1000 to about 50,000, Carbowax having a molecular weight of from 4000 to 20,000, fatty acids, sodium carboxymethyl cellulose, gelatin, fatty alcohols, clays, polymeric polycarboxylates, sodium carbonate, calcium carbonate, calcium hydroxide, magnesium oxide, magnesium hydroxide carbonate, sodium sulphate, proteins, polyvinyl alcohol, alginic acid esters, and triglycerides. Of the above, polyethyleneglycols, especially those having molecular weight of from about 1,000 to about 30,000, preferably from about 12,000 to about 30,000, and triglycerides are highly preferred.

Chelating agents beneficially aid cleaning and denture cleansing stability by keeping metal ions, such as calcium, magnesium, and heavy metal cations in solution. Examples of suitable chelating agents include sodium tripolyphosphate, sodium acid pyrophosphate, tetrasodium pyrophosphate, aminopoly-carboxylates such as nitrilotriacetic acid and ethylenediamine tetracetic acid (EDTA) and salts thereof, and polyphosphonates and aminopolyphosphonates such as hydroxyethanediphosphonic acid, ethylenediamine tetra-methylenephosphonic acid, diethylenetriaminepentamethylenephosphonic acid and salts thereof. The chelating agent selected is not critical except that it must be compatible with the other ingredients of the denture cleanser when in the dry state and in aqueous solution. EDTA and its salts, especially the tetrasodium salt, are preferred. Advantageously, the chelating agent comprises between 0.1 and 5 percent by weight of the composition and preferably between 0.2 and 2 percent. Phosphonic acid chelating agents, however, preferably comprise from about 0.1 to about 1 percent, preferably from about 0.1% to about 0.5% by weight of composition.

Enzymes suitable for use herein are exemplified by proteases, alkalases, amylases, lipases, dextranases, mutanases, glucanases etc.

EXAMPLES

The following are representative denture cleanser tablets according to the invention. The percentages are by weight of the denture cleanser tablet.

In the following examples the tablet base is made by roller compaction. The silicone-containing spray-dried powder is made as described hereinbefore. The base and the spray-dried powder are then mixed together in a tumble mixer and the tablets are made by compressing the mixture of components in a punch and dye rotary tabletting press at a pressure of about 2 x10^5 kPa.

	I	II
	%	%
GRANULATED TABLET BASE		
TAED	2.63	1.75
Sodium perborate monohydrate	17.53	18.08
Potassium monopersulphate salt[1]	48.4	51.44
Sodium carbonate	15.74	7.91
Tetrasodium EDTA	0.53	0.49
Lathanol® powder	0.66	3.40
Hydrated silica	0.28	0.1
Microcrystalline cellulose	1.11	3.0
Boeson VP 60[5]	0.71	0.2
Citric acid	4.75	1.2
Spray-dried flavour[6]	2.8	4.2
SPRAY-DRIED POWDER		
Abil® EM 90[2]	0.43	0.41
Silwet® L7230[3]	0.54	0.15
Peppermint flavour oil	0.47	0.45
Capsul E[4]	2.54	6.1
Sorbitol	0.83	0.92
Fumed Silica	0.05	0.2
Total	100	100

1 Caroat®.

2 Cetyl dimethicone copolyol from Goldschmidt.

3 Dimethicone copolyol from Union Carbide, a silicone surfactant.

4 Modified starch from National Starch & Chemical

5 Mixture of hardened triglycerides from soya oil, available from Ingelheim Boehringer

6 10% flavour oil loading on a 60:40 maltodextrin:gum acacia carrier

The denture cleansing tablets of the Examples display improved antiplaque, cleansing and anti-bacterial activity together with a long-lasting foam and high tablet strength.

CLAIMS

1. A denture cleansing composition, in tablet form, comprising a film-forming oil, an effervescence generator, from about 0.1 to about 3% of a foam-forming surfactant, and a water-insoluble, wettable, particulate foam stabiliser having a weight average particle size of from about 20 to about 400 μm, the foam stabiliser having a Foam Stabilising Index of greater than 120.

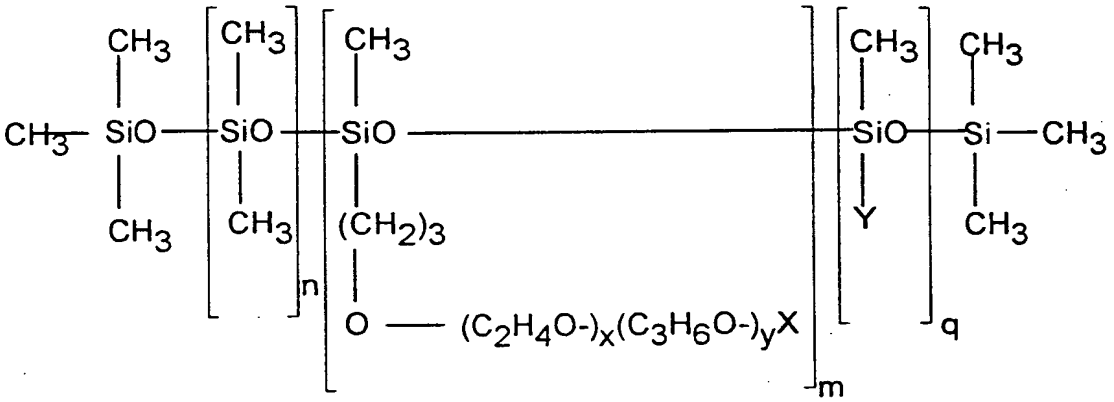
2. A denture cleansing composition according to Claim 1 wherein the foam-forming surfactant comprises an anionic surfactant.

3. A denture cleansing composition according to Claim 1 or Claim 2 wherein the foam-forming surfactant comprises sodium lauryl sulphoacetate.

4. A denture cleansing composition according to any of Claims 1 to 3 wherein the foam-forming surfactant comprises from about 0.1 to about 3%, preferably from about 0.2% to about 2%, more preferably from about 0.3% to about 1.5% by weight of the composition.

5. A denture cleansing composition according to any of Claims 1 to 4 wherein the film-forming oil is a silicone oil.

6. A denture cleansing composition according to any of Claim 6 wherein the silicone oil is of the general formula (I):



(I)

wherein X is selected from hydrogen, alkyl, alkoxy and acyl groups having from 1 to about 16 carbon atoms, Y is selected from alkyl and alkoxy groups having from about 8 to about 22 carbon atoms, n is from 0 to about 200, m is from about 1 to about 40, q is from about 1 to about 100, the molecular weight of the residue $(C_2H_4O\text{-})_x(C_3H_6O\text{-})_yX$ is from about 50 to about 2000, preferably from about 250

to about 1000 and x and y are such that the weight ratio of oxyethylene:oxypropylene is from 100:0 to 0:100, preferably from 100:0 to about 20:80.

7. A denture cleansing composition according to Claim 6 wherein the silicone oil is cetyl dimethicone copolyol.

8. A denture cleansing composition according to any of Claims 1 to 7 wherein the particulate foam stabiliser has a weight average particle size of from about 100 to about 300 μm, preferably from about 150 to about 250 μm.

9. A denture cleansing composition according to any of Claims 1 to 8 wherein the particulate foam stabiliser has a Foam Stabilising Index of greater than 140, preferably greater than 150.

10. A denture cleansing composition according to any of Claims 1 to 9 wherein the particulate foam stabiliser is microcrystalline cellulose.

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 98/22974

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K7/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 33693 A (THE PROCTER & GAMBLE COMPANY ET AL.) 31 October 1996 see examples 1-5 see page 18, line 3 - line 14 see page 17, line 18 - line 26	1-10
Y	EP 0 010 412 A (RECKITT & COLMAN PRODUCTS LIMITED) 30 April 1980 see example 3	1-10
Y	DATABASE WPI Week 7650 Derwent Publications Ltd., London, GB; AN 76-92530X XP002094741 & DD 122 326 A (J. BORGWARDT) , 5 October 1976 see abstract	1-10

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 February 1999	16/03/1999

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INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 98/22974

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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A	GB 1 579 401 A (KUKIDENT RICHARDSON-MERRELL GMBH&CO. KG) 19 November 1980 see column 3, line 106 - line 110 -----	

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